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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,520	01/21/2004	David I. Freed	06530.0309	1095

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/760,520	Applicant(s) FREED, DAVID I.	
	Examiner Matthew J. Kasztejna	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-21, 23-54 and 56-96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-21, 23-54 and 56-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on May 3, 2006, the finality of the rejection mailed March 6, 2006 is *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 11-13, 18-20, 25-26, 34, 42, 59, 69, 72-73, 75, 77, 79-80, 83, 85-87, 92 and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "sufficiently" in claims 1, 19, 34, 69, 83 and 87 is a relative term which renders the claim indefinite. The term "sufficiently" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear to what degree the elongate member is flexible.

The term "substantially" in claims 1, 11-13, 18-20, 25-26, 42, 59, 69, 72-73, 75, 77, 79-80, 83, 85-87, 92 and 96 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8, 10-18, 23-30, 33-40, 42-44, 46, 47-52, 54, 56, 58-63 and 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 6,660,011 to Levinson.

In regards to claims 1, 28, 34, 47-52, 54, 56, 58-63 and 65-68, Konomura discloses a medical device comprising: a proximal handle; an elongated member 2 having a proximal end, a distal end, and a lumen there between, the proximal end being coupled to the proximal handle, the elongated member being sufficiently flexible to traverse through tortuous anatomy of a patient's body; an end effector 6 proximate the distal end of the elongated member, actuation of the proximal handle 14 causing the end effector to perform a medical procedure; and a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member (see Figs. 1 and 2, and Col. 4, Lines 1-14). Konomura is silent with respect to a tissue cutting end effector wherein actuation of the proximal handle causes the end effector to sever tissue. Konomura teaches of wires 6 used for holding or fracturing a foreign matter. Levinson teaches of an analogous medical device used for

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tissue cutting and retrieval. The device consists of a set of wires 20 used for selectively cutting tissue within the body (see Figs. 1 and 9). It would have been obvious to one skilled in the art at the time the invention was made to have a tissue cutting end effector in the apparatus of Konomura to selectively capture, cut and/or retrieve polyps and other aggregates of organic tissue from a patient's internal organs as taught by Levinson. The apparatus of Konomura and Levinson is inherently capable of performing the recited method steps.

In regards to claim 2 and 35, Konomura discloses a medical device wherein the flow path defined by the distal member has a cross-sectional flow area less than a cross-sectional flow area of the lumen (see Fig. 2)

In regards to claims 3-4 and 36, Konomura discloses a medical device including a port 10 which is in fluid communication with the lumen and comprises a fluid supplying member for supplying fluid to the port (see Col 3, Lines 20-25).

In regards to claims 8 and 38, Konomura discloses a medical device wherein the end effector includes a snare loop 6 (see Col. 3, Lines 8-16).

In regards to claims 10-13 and 37, Konomura discloses a medical device wherein the distal member includes a sealing member 7. At least a portion of the distal member has a frusto-conical shape for substantially closing the lumen. The distal member includes a base portion and a head portion, the base portion having an outer diameter substantially the same as an inner diameter of the lumen, the head portion having an outer diameter greater than the inner diameter of the lumen. Also, the distal

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member includes a plate member having an outer diameter substantially the same as the inner diameter of the lumen (see Col. 3, Line 64 – Col. 4, Line 13).

In regards to claims 14-15, Konomura discloses a medical device wherein at least a portion of the flow path has a cross-sectional flow area smaller than that of at least one of an inlet and an outlet of the flow path (see Col. 4, Lines 36-68).

In regards to claims 16-18, 39-40 and 42-44, Konomura discloses a medical device wherein the distal member connects to the end effector at a distal end of the end effector and the distal member is movable relative to the lumen and is configured to substantially close the lumen when the end effector retracts (see Fig. 1 and Col. 4, Lines 1-14).

In regards to claims 23-27, Konomura discloses a medical device wherein the distal member is fixedly connected to a distal end of the elongated member and wherein the flow path has an inlet opening in a direction transverse to a axis of the annular body and an outlet opening in a direction substantially parallel to the axis of the annular body (see Fig. 6)

In regards to claims 28-30, Konomura discloses a medical device wherein the handle includes a stationary part 15 and movable part 14. Further comprising a control member 5 having a proximal end coupled to the movable part and a distal end coupled to the end effector so that actuation of the movable part relative to the stationary part enables movement of the end effector for performing the medical procedure (see Fig. 1 and Col. 3, Lines 26-47).

In regards to claim 33 and 46, Konomura discloses a medical device wherein the distal member defines a plurality of flow paths (see Fig. 5).

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 6,660,011 to Levinson in further view of U.S. Patent No. 5,599,324 to McAlister et al.

In regards to claims 5-7, Konomura and Levinson disclose a medical device but are silent with respect to a fluid supply member (syringe) for supplying fluid to the port, an interlocking member and fluid chamber sealed from a portion of the handle. McAlister et al. teach of an analogous device in which a physician can attach a syringe or other device to the second entry port 31 and force a contrast agent through the passage 35, the central volume 33 and the lumens 23 and 24 in parallel to be discharged where the lumens 23 and 24 exit the distal end 17. The seals formed between the tube 36 and the handle 12 and between the tube 36 and the catheter tube 11 around the guidewire 22 assure isolation of the guidewire lumen 22 (see Col. 5, Lines 13-22). It would have been obvious to one skilled in the art at the time of the invention to include a fluid supply assembly in the device of Konomura and Levinson so if it is necessary to relocate the distal tip 20, there is no need to remove the guidewire as taught by McAlister et al.

Claims 19-21, 41, 57, 83-86, 90-92 and 94-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 6,660,011 to Levinson in further view of U.S. Patent No. 6,517,539 to Smith et al.

In regards to claims 19-21, 41, 57, 83-86, 90-92 and 94-96, Konomura and Levinson disclose a medical device but are silent with respect to the distal member connected to the proximal end of the end effector. Smith et al. teach of an analogous device having a distal member 96 fixedly secured to proximal end of the end effector 24 (see Figs. 12-13). It would have been obvious to one skilled in the art at the time the invention was made to include a fixedly secured distal member in the apparatus of Konomura and Levinson in order to provide greater control over the end effector as taught by Smith et al. The apparatus of Konomura and Levinson would then be inherently capable of performing the recited method steps.

Claims 31-32, 45, 53 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 6,660,011 to Levinson in further view of U.S. Patent No. 5,575,694 to Hawkins et al.

In regards to claims 31-32, 45, 53 and 64 Konomura and Levinson discloses a medical device but are silent with respect to an electrical connector for receiving cautery current from a power supply source. Hawkins et al. teach of an electrical connector for attachment to a cauterizing endoscopic snare (see Col. 2, lines 57-67). It would have been obvious to one skilled in the art at the time the invention was made to include such an electrical connector in on the device of Konomura and Levinson in order to provide the snare loop with an electrical current and therefore assist in surgical procedures, as taught by Hawkins et al. and is well-known in the art. The apparatus of Konomura and Levinson would then be inherently capable of performing the recited method steps.

Claims 47, 59, 69-82, 87-89 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 6,660,011 to Levinson in further view of U.S. Patent No. 6,960,182 to Moutafis et al.

In regards to claims 47, 59, 69-82, 87-89 and 93, Konomura and Levinson discloses a medical device comprising: a proximal handle; an elongated member 2 having a proximal end, a distal end, and a lumen there between, the proximal end being coupled to the proximal handle, the elongated member being sufficiently flexible to traverse through tortuous anatomy of a patient's body; a tissue cutting end effector proximate the distal end of the elongated member, actuation of the proximal handle 14 causing the end effector to sever tissue; and a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member. Konomura and Levinson are silent with respect to wherein at least a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path. Konomura teach that the number of openings is not limited and that a plurality of openings may be formed through which fluid may be passed (see Col. 4, Lines 36-65). Moutafis et al. teach of a variety of analogous surgical instruments for forming a liquid jet, which are useful for performing a wide variety of surgical procedures. Moutafis et al. teach of a nozzle capable of having a large variety of configurations and cross-sectional flow paths to effect the outputted fluid (see Cols. 21

and 22 and Figs 3a-e). It would have been obvious to one skilled in the art at the time the invention was made to vary the cross-sectional flow area in the apparatus of Konomura and Levinson in order to have greater control over the outputted flow of fluid as taught by Moutafis et al.

Response to Arguments

Applicant's arguments filed May 3, 2006 have been fully considered but they are not persuasive.

It is noted that claim 93 was not addressed in the previous final rejection mailed March 6, 2006, even though the claim was indicated as being rejected in the Office Action Summary. Although the claim was not individually addressed, the limitations of the claim were addressed in the previous action since the claim is nearly identical to claim 89, which was rejected.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Levinson teaches of an analogous medical device combining a tissue cutting snare and a basket retriever in one device to cut and retrieve tissue. The device consists of a set of wires 20 used for selectively cutting tissue within the body (see Figs. 1 and 9). It would have

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been obvious to one skilled in the art at the time the invention was made to have a tissue cutting end effector in the apparatus of Konomura to selectively capture, cut and/or retrieve polyps and other aggregates of organic tissue from a patient's internal organs as taught by Levinson. Furthermore, because Konomura teach of wires 6 used for holding or fracturing a foreign matter it would have been desirable to one skilled in the art to use a set of wires 20 in the device of Konomura to selectively cut tissue within the body as taught by Levinson to assist in fracturing the foreign matter for removal, which is an objective of the device of Konomura.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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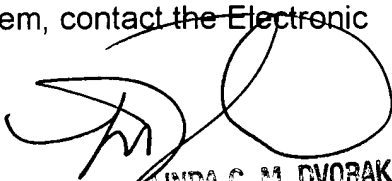
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJK *MJK*
5/15/06


LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700